SECTION 1. THE FSIS NATIONAL RESIDUE PROGRAM

The regulatory system that enforces the U.S. food safety laws has been evolving since 1906. This system helps to protect the public from foodborne hazards and has enabled the food produced in the U.S. to be among the safest in the world. Nevertheless, maintaining the wholesomeness and safety of the food supply requires continued vigilance and the flexibility to adapt to changing conditions.

On July 25, 1996, the U. S. Department of Agriculture published the *Final Rule on Pathogen Reduction; Hazard Analysis and Critical Control Point (PR/HACCP) Systems*. The principal focus of this rule, which complements existing food safety laws and regulations, is to reduce both the pathogenic organisms on meat and poultry products and the incidence of foodborne illness associated with these products. The presence in food of chemical residues above permitted levels causes the food to be adulterated under the Federal Food, Drug, and Cosmetic Act (FFDCA). Under the Federal Meat Inspection Act (FMIA), the Poultry Products Inspection Act (PPIA), and the Egg Products Inspection Act (EPIA), slaughter and production establishments bear responsibility for ensuring that their product is not adulterated when it enters commerce. Part 417 of the PR/HACCP regulation requires meat and poultry establishments to develop and implement a system of preventive measures designed to ensure the safety of their products. In developing their HACCP plans, slaughter establishments must address all chemical, physical, and biological hazards that are reasonably likely to occur in the animals that enter their plants. Section 417.2 requires that slaughter establishments conduct a hazard analysis to determine the food safety hazards reasonably likely to occur before, during, and after entry into the establishment. The preamble of the rule describes the potential hazards that plants need to consider during a hazard analysis. These hazards include chemical residues resulting from use of or exposure to animal drugs, pesticides and environmental contaminants. The rule also provides a new framework for the modernization of the meat and poultry inspection system.

A vigilant chemical residue prevention program is essential to fostering the prudent use of drugs and pesticides in animals that enter the human food supply. The requirement that slaughter establishments implement HACCP systems is a significant step in this evolutionary process.

HACCP implementation does not remove or diminish the regulatory authority of FSIS. FSIS inspectors will continue to condemn animals for cause, and FSIS will continue to cooperate with the Food and Drug Administration (FDA) and/or the Environmental Protection Agency (EPA) as a part of follow-ups to residue violations. Any tissue containing a residue that exceeds its specified tolerance or action level, or that contains a residue that has been banned from use in food animals, is considered to be in violation of FFDCA.

When violative residues are detected in food-producing animals submitted for slaughter, FSIS notifies the producer and any parties involved in offering these animals for sale. These parties are subject to follow-up enforcement testing until compliance is demonstrated. Product found to contain violative levels of residues is considered adulterated and is subject to condemnation. If the product has been distributed into commerce, it may be subject to market recall. In addition, FDA and cooperating state agencies may make on-site visits to these firms. Typically, an educational visit by the state is the first step in attempting to correct a residue problem. If the problem is not corrected, subsequent visits, made by FDA, could result in enforcement action, including prosecution.

FSIS enforces the tolerances and action levels set by FDA and EPA. FDA has statutory authority for setting tolerances and/or action levels for veterinary drugs under the FFDCA, as codified under 21 CFR

Part 556 and 109. EPA has statutory authority for setting tolerances and/or action levels for pesticides under the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA) and FFDCA, as modified by FQPA; codified under 40 CFR. Chemical hazards also may be associated with substances that occur in meat, poultry, and egg products as a result of environmental contamination. EPA reviews exposure and toxicology data and may make recommendations to FDA and FSIS on the appropriate action levels for canceled pesticides and other environmental contaminants present in the environment.

The cornerstone of FSIS residue prevention activities is the FSIS National Residue Program (NRP), a multi-component analytical testing program for residues in domestic and imported meat, poultry, and egg products.[1] The NRP provides a variety of sampling plans to verify that slaughter establishments are fulfilling their responsibilities under HACCP for preventing violative residues and develops national data for chemical residues to support risk assessment, enforcement and educational activities. The range of chemical compounds considered for inclusion in the various NRP testing programs is comprehensive in scope. It includes approved and unapproved pharmaceutical drugs and pesticides known or suspected to be present in food animals in the U.S. and in countries exporting products to the U.S. It also includes any other xenobiotic or naturally occurring compounds that may appear in meat, poultry and egg products and that may pose a potential human health hazard.

The prevention of illegal chemical residues in the food supply is an integral aspect of maintaining a high level of food safety. High consumer expectations necessitate that the U.S. thoroughly document the safety of our meat, poultry, and egg products. In addition, issues related to chemical residues in food may hinder the export of U.S. food products.

The NRP is designed to provide: (1) a structured process for identifying and evaluating compounds of concern by production class; (2) the capability to analyze for compounds of concern; (3) appropriate regulatory follow-up of reports of violative tissue residues; and (4) collection, statistical analysis, and reporting of the results of these activities.

The goals of the NRP to:

- Enforce Federal laws and regulations;
- Maintain consumer confidence by ensuring that meat, poultry, and egg products are not adulterated;
- Act as a deterrent against the slaughter of adulterated animals and the processing of adulterated eggs; and
- Assess and communicate human exposure to chemical residues.
- Provide verification of residue control in HACCP systems.

[1]The production classes for which FSIS has regulatory authority are: horses, bulls, beef cows, dairy cows, heifers, steers, bob veal calves, formula-fed veal, non-formula-fed veal, heavy calves, sheep, lambs, goats, market hogs (including roaster pigs), boars/stags, sows, young chickens, mature chickens, young turkeys, mature turkeys, ducks, geese, rabbits, and egg products (liquified eggs and dried eggs).

SECTION 2. COMPONENTS OF THE FSIS NATIONAL RESIDUE PROGRAM

DOMESTIC RESIDUE SAMPLING PROGRAM

The Food Safety and Inspection Service (FSIS) National Residue Program (NRP) provides a variety of sampling plans to verify and enforce that slaughter establishments are fulfilling their responsibilities under the Hazard Analysis and Critical Control Point (HACCP) regulation, and in accordance with Food and Drug Administration (FDA) and Environmental Protection Agency (EPA) regulations, to prevent the occurrence of violative residues. The NRP also collects and uses national data on chemical residues to support risk assessment, enforcement, and educational activities. All residue data is collected and stored in the Microbiological and Residue Computer Information System (MARCIS). Detailed information on violations is immediately transferred to the Residue Violation Information System (RVIS), which facilitates regulatory follow-up on violations and tracking of residue violators by both FSIS and FDA.

Components of the NRP for domestically produced products include:

- Monitoring Plan– the random sampling of specified animal populations at time of slaughter to provide more information about the occurrence of residue violations on an annual, national basis.

- Special Projects – information gathering studies that do not meet the criteria for inclusion in the monitoring plan, e.g. when sampling will not be conducted over a full 12-month period, or when there is a lack of precise slaughter volume data on the production classes to be sampled. This designation is also used when it is not possible to define a "violation rate" for a compound because the violative level has not been defined. For example, when trace metals, such as cadmium or lead, are detected in edible tissues, a Special Project may be initiated to develop information on the frequency and concentration at which these residues occur.

- Surveillance Sampling – targeted sampling designed to distinguish components of livestock, poultry, and egg products in which residue problems exist, measure the extent of problems, and evaluate the impact of actions taken to reduce the occurrence of residues. Surveillance Sampling is considered a subset of Special Projects except that, unlike Special Projects, Surveillance Sampling sometimes employs on-site rapid screening tests.

- Enforcement Testing – the analysis of specimens collected from individual animals or lots that appear suspicious to FSIS in-plant inspectors, based on herd history or antemortem or postmortem inspection. Enforcement Testing is also used to follow up on producers that have marketed animals with violative concentrations of residues, to determine if the non-compliance has been corrected or to verify industry's HACCP system.

It is important to emphasize the differences between the types of samples collected under the Monitoring Plan and Special Projects, as compared with those collected under Enforcement Testing. Since the former are designed to collect information upon the rate of residue violations in the U.S. food supply, these plans sample only those carcasses that have been inspected and passed. In other words, Monitoring Plan and Special Project samples are collected only from animals that appear normal and healthy at time of slaughter, and are thus permitted entry to the food supply. By contrast, Enforcement Testing specifically targets animals that do not appear to be normal or healthy, or that show postmortem signs, and thus includes samples from animals that are condemned based on antemortem or postmortem inspection.

In addition, because carcasses sampled under Enforcement Testing are by definition "suspect," and because a principal goal of Enforcement Testing is to prevent adulterated meat from entering the food supply, all carcasses sampled under Enforcement Testing are held pending the results of official laboratory testing (unless on-site screening tests, described below, show them to be negative, or unless they have already been condemned by the inspector for other reasons). Carcasses found to contain violative concentrations of residues are considered adulterated and condemned. By contrast, carcasses sampled under the Monitoring Plan and Special Projects are not held pending the results of testing. This is because the primary purpose of these sampling plans is information gathering (and identification of emerging residue problems), rather than direct removal of violative product from the food supply. Additionally, carcasses tested under the Monitoring Plan and Special Projects are unlikely to be violative; the median violation rate across all combinations of compound classes and production classes for carcasses sampled in these plans is below 0.3%.

Finally, because the Monitoring Plan and Special Projects are designed to generate statistical data on nationwide residue violation rates, all samples collected under these plans must be sent directly to the FSIS laboratory for testing, without first being screened on-site by inspectors (if only screen-positive samples were sent to the laboratory, this would bias the results). By contrast, Enforcement Testing makes extensive use of rapid on-site screening tests. Because FSIS in-plant inspectors are required to subject all carcasses for which there is a suspicion of a residue violation to Enforcement Testing, a very large number of such tests are performed, typically between 100,000 and 200,000 annually. However, it is not practical for FSIS to carry out expensive and time-consuming laboratory tests on this many Enforcement samples each year. Therefore, to perform such a large number of tests efficiently, carcasses are first pre-screened on-site by FSIS inspectors using rapid screening tests, where such tests are available. In this way, only those samples that test positive by a screening test (again, where such tests are available) are sent to an official laboratory for follow-up testing. If an FSIS inspector suspects that a carcass may contain a violative level of a residue not detected by an official FSIS screening method (see below), a sample taken from that carcass is sent directly to an official laboratory for testing.

As explained above, the use of on-site rapid screening tests also facilitates rapid decisions on carcass disposition. A carcass that registers a positive result on the screening test is held pending the outcome of laboratory testing, while one that registers a negative result is permitted to enter the food supply (unless the FSIS inspector has condemned it for some other reason).

FSIS currently employs the following on-site rapid screening tests:

1. SOS (Sulfa-On-Site) – tests swine urine for sulfonamide residues.
2. CAST (Calf Antibiotic & Sulfonamide Test) – swab test on kidney or liver tissue of bob veal calves (less than 3 weeks of age and under 150 lbs.).
3. STOP (Swab Test on Premises) – tests for antibiotic residues in kidney tissue in all production classes of cows, chicken, hogs, turkeys and sheep.
4. FAST (Fast Antimicrobial Screen Test) – swab test on kidney or liver tissue of cows and bob veal for antibiotic and sulfonamide residues.

Contamination Response System

The Contamination Response System (CRS) is not a testing plan, but is rather an emergency response management system for FSIS, FDA, and EPA. There are certain pesticides and environmental contaminants whose detection may suggest the occurrence of a potential risk to consumers. To ensure against this, detection of these residues immediately initiates a rapid follow-up investigation to characterize and address the residue problem. Actions taken may include investigation of any entity from the producer to the retailer and, if needed, withdrawal of the product from the market. This system is also triggered following the detection of banned veterinary drugs.

IMPORT RESIDUE SAMPLING PROGRAM

The Federal Meat Inspection Act (FMIA), Poultry Products Inspection Act (PPIA), and Egg Products Inspection Act (EPIA) require foreign countries that export meat, poultry, or egg product to the U.S. to establish and maintain inspection systems that are equivalent to those of the United States. Countries must undergo a rigorous review process before they can become eligible to export meat, poultry and egg products to the U.S. Once a country is determined to be eligible, the foreign inspection system is responsible for certifying individual establishments to FSIS. FSIS periodically reviews the inspection program of the country to ensure it remains equivalent to the U.S. system. Reinspection of product at the U.S. port-of-entry, is an additional check on the effectiveness of the foreign country's inspection system.

The principle underlying FSIS import activities is a "*systems approach*," which focuses on whether the foreign country's overall inspection system is equivalent to the U.S. system. FSIS audits foreign systems to verify that the exporting country's sanitary measures achieve the U.S. inspection system's appropriate level of protection.

Residue control is a major feature of an inspection system that must be judged equivalent to the U.S. system before a country becomes eligible to export to the U.S. Foreign countries exporting to the U.S. are required to have residue control standards that lead to equivalent protection from food hazards as those of the U.S. These may include the following:

- Random sampling of animals at slaughter.
- Use of approved testing methods.
- Testing appropriate target tissues, even though such tissue may not be exported to the U.S.
- Testing for compounds identified as potential contaminants of meat exported to the U.S.
- Random sampling of eggs presented for processing

After a foreign country is determined to have an equivalent system of inspection and becomes eligible to export product to the U.S., FSIS relies on the country's national inspection authorities to certify that establishments meet all applicable standards and are authorized to export to the U.S. FSIS audits the foreign inspection system, depending on a country's performance history, including previous plant reviews and product reinspection at the port of entry. If a country does not continue to operate an inspection system equivalent to the U.S. system, including the 1996 *Final Rule on Pathogen Reduction; Hazard Analysis and Critical Control Point (HACCP) Systems*, it is removed from the official list of countries eligible to export to the U.S. This list is published in the Federal Register.

As a further check on the effectiveness of the foreign inspection system, FSIS randomly samples meat, poultry, and egg products for reinspection at the U.S. port of entry. Sampling at the port of entry is based on the Import Residue Plan designed by FSIS.

Reinspection of meat and poultry is directed by the Automated Import Information System (AIIS), which stores reinspection results from all port-of-entry samples for each country and for each plant.

Reinspection of products is performance-based, which means that better performing foreign establishments are subject to less frequent reinspection by FSIS inspectors at official import establishments. All shipments are reinspected for transportation damage, labeling, proper certification, general condition, and accurate count. The AIIS assigns a variety of types of sample inspections , which may include analysis for chemical residues. Residue analyses are not limited to those compounds included in the domestic residue program. FSIS can initiate a special sampling plan when there is a need to monitor a country for residues of a specific compound, based on detection of violative residues at port of entry, or other information concerning risk to human health. Decisions about product acceptability are based on U.S. tolerances or action levels.

For egg products, the first ten shipments from individual foreign establishments are subjected to 100 percent reinspection, to establish a history of compliance for each product category. This rate is reduced to a random selection of one reinspection out of eight shipments, which continues as long as the product is in compliance.

Shipments that are sampled during routine monitoring are eligible to be stamped with the U.S. mark of inspection and allowed to enter commerce prior to receipt of the results of the analysis. If the importer chooses to voluntarily hold the shipment until the results are received, the shipment is stamped "U.S. Refused Entry" when violative results are reported, and must be exported from the United States, destroyed, or converted to animal food if an appropriate approval is received from FDA. However, if violative results are reported, imported product bearing the U.S. mark of inspection will not be eligible for export from the U.S.

SECTION 3. PLANNING THE 2000 FSIS NATIONAL RESIDUE PROGRAM: INTRODUCTION

The Food Safety and Inspection Service (FSIS) has focused special attention on the planning of the Monitoring Plan and Special Projects for domestic products, and upon the Import Residue Plan for imported products, since these are the Agency's principal source of information on the occurrence of residues in meat, poultry, and egg products. The remainder of this document will explain how FSIS designed the 2000 FSIS National Residue Program (NRP) Domestic Monitoring Plan and Special Projects, and Import Residue Plan, and will provide a complete listing of the residues and production classes that are sampled under these programs.

The first step in the design of these sampling plans is to generate a comprehensive list of residues of concern in meat, poultry and egg products. To accomplish this, the Emerging Issues Branch (EIB), Chemistry and Toxicology Division[1], Office of Public Health and Science, FSIS, coordinates annual meetings of the Surveillance Advisory Team (SAT)[2], comprised of members from the Environmental Protection Agency (EPA), the Food and Drug Administration (FDA), the Centers for Disease Control (CDC), and the United States Department of Agriculture (USDA). This interagency committee identifies the priority public health compounds of concern, and provides EIB with detailed information about each compound. EIB then combines this information with FSIS data on compound violation rates to develop the domestic Monitoring Plan and Special Projects and the Import Residue Plan. These sampling plans guide the allocation of FSIS laboratory and inspection resources.

Factors taken into consideration in developing the domestic Monitoring Plan and Special Projects are:

A. the relative public health concern of residues and their potential presence in meat, poultry, and egg products;
B. the production or product classes in which residues are of most concern;
C. the availability of analytical methods, which determines which compounds or compound classes can be analyzed; and
D. the analytical capacity of the FSIS laboratories, which determines how many analyses can be performed for each compound or compound class.

Thus the final form of the scheduled sampling plans are determined not only by the estimated relative public health risk represented by each combination of residue and production class, but also the availability of methods and resources to sample for these residues. FSIS attaches a high priority to obtaining new or improved methods for highly ranked residues.

The selection process used to design the Import Residue Plan is similar to that of the domestic plans, with two important exceptions.

First, since many countries ship processed products only, it is often not possible to test raw product at the U.S. Port of Entry. Further, even when raw product is shipped, it often consists of muscle tissue only. By contrast, domestic residue testing often is targeted towards organ tissues (typically kidney and liver). This is because many residues concentrate in organs, which makes them easier to detect. Further, because

1 On July16, 2000 Office of Public Health and Science, FSIS underwent a reorganization in which responsibility for the design of the residue program was shifted to the Residue Branch, Food Animal Sciences Division.
[2]A detailed list of SAT participants is provided at the end of this section.

of this concentration effect, FDA often bases its tolerances for veterinary drugs upon the levels found in kidney or liver.

Second, while countries are required to identify the animal species used in each product, they are not required to identify the production class. Testing on imported meat and poultry, while subdivided by animal species (e.g., chicken vs. pig), therefore cannot be further subdivided within a species (e.g., steer vs. heifer vs. dairy cow. vs. formula-fed veal). Egg products, however, can be distinguished as a separate category.

Finally, because different countries have different approved drugs and different drug use practices, the compounds analyzed in the Import Residue Plan are not necessarily the same those in the Domestic Monitoring Plan and Special Projects.

SURVEILLANCE ADVISORY TEAM (SAT)

PURPOSE

The SAT participants identify:

- The "universe" of compounds,
- Specific residues of public health concern,
- Analytical residue method development needs
- Emerging issues for chemical hazards

CHAIR

- Director, Chemistry and Toxicology Division, Office of Public Health and Science (OPHS), FSIS, USDA

PARTICIPANTS

- Health Effects Division, Office of Pesticides, Prevention, and Toxic Substances, EPA

- Center for Food Safety and Applied Nutrition, FDA, Department of Health and Human Services (HHS)
- Center for Veterinary Medicine, FDA, HHS
- Centers for Disease Control and Prevention, HHS

- Animal and Plant Health Inspection Service, USDA
- Science and Technology, Agricultural Marketing Service, USDA
- Agricultural Research Service, USDA

- Chemistry and Toxicology Division, OPHS, FSIS, USDA
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- Field Service Laboratories, OPHS, FSIS, USDA
- Technical Service Center, Office of Field Operations (OFO), FSIS, USDA
- Federal-State Relations Staff, OFO, FSIS, USDA
- Animal Production Food Safety Program, Office of Policy, Program Development and Evaluation (OPPDE), FSIS, USDA
- Domestic Policy Development and Evaluation Division, OPPDE, FSIS, USDA
- International Policy Division, OPPDE, FSIS, USDA
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